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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/627,796	07/28/2000	Krishan L. Taneja	BP9806US-CP2	3581

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EXAMINER	
SITTON, JEHANNE SOUAYA	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/627,796	TANEJA, KRISHAN L.	
	Examiner	Art Unit	
	Jehanne Souaya Sitton	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) *16-20 and 24-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1, 3-11, 13-15, 21-23, 29-45 is/are rejected.

7)☒ Claim(s) 2, 12, 37, 41 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a)☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8/2000*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet.*

Continuation of Attachment(s) 6). Other: 1449: 5/2001; 10/2003; "Revised Amendment Practice".

DETAILED ACTION

1. Currently, claims 1-45 are pending in the instant application. Claims 16-20 and 24-28 are withdrawn from consideration as being drawn to non elected inventions. Claims 1-15, 21-23 and 29-45 with regard to chromosome Y and SEQ ID NOS: 10-16, (see office action mailed 4/21/2003; Section 2) are under consideration at this time. It is noted that the claims under consideration have not been amended to reflect the election and are drawn to probe compositions that have not been elected, searched, or considered. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. Any rejections not reiterated are hereby withdrawn. The following rejections are maintained in part from the previous office action, however as the claims have been amended, the rejections also contain new grounds of rejection with regard to such amendments. Such rejections are therefore placed under the heading "New Grounds of Rejection". They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is NON-FINAL.

2. It is noted that the response designates claim 16, for example, as presently amended when this claim should be designated as "withdrawn", even though the claim is presently amended. See the attached guidelines regarding the correct submission of amendments. In order to expedite prosecution of this application, claims 16-20 and 24-28 have been regarded as "withdrawn" and a "Notice of non responsive amendment" will not be sent. However, in subsequent amendments, the claims should be designated as set forth in the guidelines.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

4. Claims 2 and 12 are objected to for being dependent on rejected claims. These claims are further objected to because while being free of prior art and paragraph 112 rejections, such claims are not allowable as they encompass non-elected inventions.

Claim 37 contains an extra word "at" which should be deleted as it does not appear to with the rest of the wording of the claim.

Claim 41 does not appear to further limit claim 36. Claim 36 recites one "non nucleic acid probe" however claim 41 has been amended to recite "a PNA probe". It appears that claim 41 should be likewise amended to recite "a PNA probe" for antecedent basis with the independent claim.

Information Disclosure Statement

5. The response at page 2 states that the Examiner did not return PTO-Form 1449 for the documents submitted August 19, 1999, January 4, 2000 and August 14, 2000. The examiner has thoroughly reviewed the case and found 1449 forms submitted August 14, 2000 and May 22, 2001. These forms correspond to the courtesy copies provided by applicant. These forms along with the 1449 submitted October 14, 2003 have been considered, initialed, and signed by the examiner and are submitted with this office action. However, the examiner could not find any 1449's dated August 19, 1999 or January 4, 2000. As this instant application was filed July 28,

2000, it appears that reference to such dates (before the instant filing date and date the application papers were submitted) may be with reference to another application. However, if reference to such dates was not incorrect, applicant is requested to include a copy of such 1449's along with a return receipt postcard, for proper review by the office.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

6. Claims 1, 3-11, 13-15, 21-23, and 29-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a PNA probe or probe set comprising PNA probes with the specific PNA formula set forth in the claims consisting of nucleobases of SEQ ID NOS 10-16, does not reasonably provide enablement for A) a PNA probe or a probe set comprising PNA probes of 10-30 subunits with the specific PNA formula set forth in the claims but with any nucleobase portion suitable for identifying, or enumerating human chromosomes Y or B) the probe set of A comprising PNA probes with the specific PNA formula set forth in the claims but "comprising" a probing nucleobase sequence at least a portion of which is at least ninety percent homologous to the nucleobase sequence or their complements of SEQ ID NOS 10-16, or to kits comprising or methods of using such PNA probes or PNA probe sets. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims broadly encompass a PNA probe or probe set comprising PNA probes with the specific PNA formula set forth in the claims but with as little as 10 subunits and up to 30

subunits and any nucleobase portion suitable for identifying, or enumerating human chromosome Y or said probe or probe set comprising PNA probes with the specific PNA formula set forth in the claims but "comprising" a probing nucleobase sequence at least a portion of which is at least ninety percent homologous to the nucleobase sequence or their complements of SEQ ID NOS 10-16. The claims are further drawn to kits comprising or methods of using such PNA probes or PNA probe sets.

The specification teaches the specific constructs of table 2 with the specific nucleobase containing portions outlined in the specification, that is "consisting" of SEQ ID NOS 1-118. The specification demonstrates the use of such probes as chromosome specific probes. However, the claims are of a much broader scope, such that the specification does not enable the skilled artisan to predictably make or use the claimed products in methods of detecting, identifying, or enumerating specific chromosomes.

The specification teaches that the nucleobase sequence of the non nucleic acid probes is the sequence recognition portion of the construct. Probes encompassed by all of the claims include for example, PNA probes of 10-30 subunits. While the specific probes of table 2 have been shown to be specific for identifying a chromosome, it is unpredictable as to whether altered nucleobase containing PNA probes which can comprise minimally "any" 10 to as many as 30 subunits, or wherein the 10-30 subunits comprise a probing nucleobase sequence at least a portion of which is only "at least" 90% homologous to the recited SEQ ID NOS: would be specific for identifying a chromosome. With regard to probes having as little as 10 or even 11 or 15, 16 subunits, etc with any nucleobase composition, or a specific nucleobase composition, including PNAs, it is unpredictable as to whether such a sequence would be specific for a

particular chromosome and therefore be capable of identifying, enumerating, or detecting any specific chromosome, including those set forth in the claims. A 10 mer sequence, or even 11, or 16 mers, etc, would be expected to appear numerous times throughout the genome, thus identifying a variety of nucleic acid sequences that are not specific for a particular chromosome. Given that there are 3000 billion nucleotides in the human genome, one would statistically expect a 10 mer, for example, to occur every million nucleotides. This results in any particular 10 mer nucleobase portion occurring 3000 times in genomic sequences. However, the specification has provided no guidance as to which specific nucleobase portion, other than those designated by SEQ ID NO, would be capable of exhibiting specificity for a particular chromosome. While the skilled artisan would be able to envision some constructs that would seemingly be specific for a particular chromosome using sequence comparison with the known sequences in Genbank, the specification teaches that in functional assays, "many of the sequences originally chosen did not prove to be highly specific despite alignment analysis indications that they should be specific to the chromosome sought to be detected" (see p. 24, lines 6-8 of the specification). Therefore, the specification teaches of the unpredictability in designing chromosome specific probes. Given such teachings, the skilled artisan would not be able to predictably determine the identity of the probing nucleobase containing portions of the probes encompassed by the claims which would be able to function in identifying, detecting, or enumerating human chromosomes Y in a sample, other than by specific SEQ ID NO.

Claims 10, 21, 34, 35, and 45 encompasses products with no specifically defined nucleobase structure and claims 1, 3-9, 11, 13-15, 22, 23, 29-33, and 36-44 are drawn to probes with only a partially defined probing nucleobase sequences, and such products, while being able

to detect a certain chromosome would not necessarily be specific for detecting chromosome Y, for example. Probes of 10-30 subunits "comprising" a probing nucleobase sequence where only a portion are at least 90% homologous to the nucleobase sequence of SEQ ID NO 10 encompasses a probe with altered nucleobase containing portions, wherein it is unpredictable as to whether such a probe would be able to be used to detect chromosome Y, for example. However, due to the lack of guidance from the specification and the unpredictability taught in the specification with regard to constructing probes which can be used to identify a *specific* chromosome based even on already known nucleic acid sequences from chromosomes, undue experimentation would be required of the skilled artisan to make and use the extremely large number of different molecules encompassed by the broad scope of the claimed invention. A large amount of unpredictable trial and error analysis would be required for the skilled artisan to make and use probes as encompassed by the claims. Such experimentation is considered undue.

Response to Arguments

The response asserts that the claims have been amended to define PNA probes of a defined length and a defined structure. This amendment was not sufficient to overcome the rejections, however, because amended claims still encompass probes with undefined or only partially defined nucleobase structures. As the nucleobase structure is what imparts the use of the probes for identifying a *specific* chromosome, the claims still encompass a large number of PNA probes which are not predictably capable of detecting a specific chromosome. As the specification has not defined what part of the of the nucleobase containing portion imparts such specificity, other than the full nucleobase containing portion set forth in the sequence identifiers, or which nucleobases can be altered (deleted, added, changed) and still impart such specificity to

the probe for a particular chromosome, a large amount of unpredictable trial and error analysis would be required to make and use the broad scope of the encompassed PNA probes. The amendment to the claims has been sufficient to overcome the rejection with regard to claims 2 and 12 as these claims are drawn to a single PNA probe or PNA probe set comprising any one of SEQ ID NOS 10-16 or all of SEQ ID NOS 10-16, respectively, with the PNA formula set forth in the claims wherein the probing nucleobase sequence for each probe is the sequence of each SEQ ID NO.

Written Description

7. Claims 1, 3-11, 13-15, 21-23, and 29-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims broadly encompass a PNA probe or probe set comprising PNA probes with the specific PNA formula set forth in the claims but with as little as 10 subunits and up to 30 subunits and any nucleobase portion suitable for identifying, or enumerating human chromosome Y or said probe or probe set comprising PNA probes with the specific PNA formula set forth in the claims but "comprising" a probing nucleobase sequence at least a portion of which is at least ninety percent homologous to the nucleobase sequence or their complements of SEQ ID NOS 10-16. The claims are further drawn to kits comprising or methods of using such PNA probes or PNA probe sets.

The specification teaches that a use for the probes of the claimed invention are for improving the specificity, sensitivity and reliability of probe based assays for the detection of chromosomes Y. The specification teaches the specific constructs of table 2 with the specific nucleobase containing portions outlined in the specification, that is "consisting" of SEQ ID NOS 1-118. The specification demonstrates the use of such probes as chromosome specific probes. The specification teaches that the nucleobase sequence of the non nucleic acid probes is the sequence recognition portion of the construct. While the specific probes of table 2 have been shown to function as specific for identifying a particular chromosome, the specification does not teach of a predictable structure/function correlation between PNA probes which are minimally 10 and up to 30 subunits with "any" nucleobase containing portion or wherein the 10-30 subunits comprise a probing nucleobase sequence at least a portion of which is only "at least" 90% homologous to the recited SEQ ID NOS: would be specific for identifying a chromosome. With regard to probes having as little as 10 or even 11, 15, 16 subunits, etc with any nucleobase composition, or a specific nucleobase composition, including PNAs, the specification does not teach whether any such sequence would be specific for a particular chromosome and therefore be capable of identifying, enumerating, or detecting any specific chromosome, including those set forth in the claims. A 10 mer sequence, or even 11, or 16 mers, etc, would be expected to appear numerous times throughout the genome, thus identifying a variety of nucleic acid sequences that are not specific for a particular chromosome. Given that there are 3000 billion nucleotides in the human genome, one would statistically expect a 10 mer, for example, to occur every million nucleotides. This results in any particular 10 mer nucleobase portion occurring 3000 times in genomic sequences. However, the specification has provided no guidance as to which specific

nucleobase portion, other than those designated by SEQ ID NO, would be capable of exhibiting specificity for a particular chromosome. While the skilled artisan would be able to envision some constructs that would seemingly be specific for a particular chromosome using sequence comparison with the sequences in Genbank, the specification teaches that in functional assays, "many of the sequences originally chosen did not prove to be highly specific despite alignment analysis indications that they should be specific to the chromosome sought to be detected" (see p. 24, lines 6-8). Therefore, the specification teaches of the unpredictability in designing chromosome specific probes. Given such teachings, the skilled artisan would not be able to envision the detailed nucleobase containing portions of the probes encompassed by the claims which would be able to function in identifying, detecting, or enumerating human chromosome Y in a sample, other than by specific SEQ ID NO.

Further, amended claims 10, 21, 34, 35, and 45, for example, are drawn to probes with no specifically defined probing nucleobase sequences with as little as 10, 11, 15, etc subunits, and claims 1, 3-9, 11, 13-15, 22, 23, 29-33, and 36-44 are drawn to probes with only a partially defined probing nucleobase sequences. Probes encompassed by these claims include probing nucleobase sequences from any part of the genome, including millions of sequences some of which were undefined at the time the specification was filed. However, the probes with sequences outlined in table 2 are not representative of the millions of sequences encompassed by the claims.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry,

whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Response to Arguments

The response asserts that the claims 10, 21, 34, 35, and 45 have been amended to define the PNA structure and that the methods disclosed in the specification for generating sequences suitable for chromosome determination using PNA probes fully support the scope of the presently claimed subject matter. This argument has been thoroughly reviewed but was found unpersuasive because the amendment to claims 10, 21, 34, 35, and 45 have not further defined the nucleobase containing portion of the probe which the specification teaches is the sequence recognition portion of the construct. As amended the claims are still drawn to probes with no specifically defined probing nucleobase sequences, although the PNAs now have a length limitation with regard to number of subunits, and amended claims 1, 3-9, 11, 13-15, 22, 23, 29-33, and 36-44 are drawn to probes with only a partially defined probing nucleobase sequences, probes encompassed by these claims include probing nucleobase sequences from any part of the genome, including millions of sequences some of which were undefined at the time the specification was filed. However, the probes with sequences outlined in table 2 are not representative of the millions of sequences encompassed by the claims. The specification has not defined or described what part of the of the nucleobase containing portion imparts such specificity, other than the full nucleobase containing portion set forth in the sequence identifiers, or which nucleobases can be altered (deleted, added, changed) and still impart such specificity to the probe for a particular chromosome, such as chromosome Y for example. In addition, the

specification provides no demonstration of possession of a set of PNA probes, with 10, or 11, or 16, etc, subunits that are specific for any chromosome or capable of identifying, enumerating, or detecting a specific chromosome or chromosomes. As such, the claims remain rejected under 35 USC 112/first paragraph. The amendment to the claims has been sufficient to overcome the rejection with regard to claims 2 and 12 as these claims are drawn to a single PNA probe or PNA probe set comprising any one of SEQ ID NOS 10-16 or all of SEQ ID NOS 10-16, respectively, with the PNA formula set forth in the claims wherein the probing nucleobase sequence for each probe is the sequence of each SEQ ID NO.

Indefinite

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 41 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 41 recites "one non nucleic acid probe". However, it is unclear if the claim is drawn to a kit comprising an extra non nucleic acid probe which is different from a PNA probe or if the 'non nucleic acid probe' refers to the "PNA probe" of claim 36 (Claim 36 was amended to recite "PNA probe" instead of "non nucleic acid probe"). The metes and bounds of the claim are unclear.

Claim 44 is indefinite as it claims an assay and only describes "use" of probes without setting forth any active method steps. An assay is generally considered a method, however, from the lack of active, positive steps, it appears that it may be intended as a composition. Thus it is

unclear if the claim is drawn to a method or a composition. The rejection can be overcome by amending to either recite a composition, or to amend the claim to include active positive steps, delimiting how the use is actually practiced.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 10, 34, 35, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Hyldig Neilsen (WO 95/32305; hereinafter referred to as Hyldig-Nielsen. It is noted that in the previous office action, a US patent was also cited to Hyldig-Nielsen. Hereinafter, any reference to Hyldig-Nielsen will be to the WO document).

It is noted that claims 10, 34, 35, and 45 recite PNA probe sets and kits to PNA probes with no particular nucleobase containing portion. It is further noted that the use for the probe sets and kits have been given no patentable weight.

Hyldig-Nielsen teaches a set of at least 13 PNA probes of 10-30 subunits in length with a nucleobase containing portion as set forth in tables 1 and 4 and teaches kits comprising PNA probes (page 26, line 28). It is noted that the amended recitation of "which is suitable for detecting, identifying or enumerating chromosomes..." as well as "prenatal kit for the multiplex analysis of human chromosomes..." is considered an intended use, and has been given no patentable weight. However, even if such was given weight, as the chromosomes listed comprise millions upon millions of different sequences, the ability of a probe within the set of Hyldig-Nielsen to hybridize to one of the chromosomes listed in the claim is considered a

property of the teachings of Hyldig Nielsen and therefore meets the limitation of "detecting, identifying or enumerating chromosomes ..." or "analysis of human chromosomes...".

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1, 3-9, and 36-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Von Wintzingerode et al (hereinafter referred to as Von Wintzingerode; FEMS Microbiology Ecology, vol. 24, pp 201-209, 1997; abstract and sequence information provided) in view of Hyldig-Nielsen et al (WO 95/32305; hereinafter referred to as Hyldig-Nielsen. It is noted that in the previous office action, a US patent was also cited to Hyldig-Nielsen. Hereinafter, any reference to Hyldig-Nielsen will be to the WO document).

It is noted that for the following rejection, the use for either the probes or kits has been given no patentably weight as such only reflects an intended use for the products and kits. With regard to claim 44, it has been interpreted to be a composition comprising at least one PNA probe.

The claims are drawn to a PNA probe of 10-30 subunits in length wherein the probe comprises a probing nucleobase sequence *at least a portion of which* is at least 90% homologous to any one of SEQ ID NOS 10-16 or their complements. Von Wintzingerode teaches a nucleic acid sequence which comprises a probing nucleobase sequence at least a portion of which is at

least 90% homologous to SEQ ID NO: 10. The sequence of Von Wintzingerode is 20 nucleotides long and at positions 2-10, is identical to instant SEQ ID NO: 10 at positions 4-12 (9 out of 10 nucleobases; 90% identity). Therefore, a portion of the sequence of Von Wintzingerode is at least a 90% identical to SEQ ID NO: 10 (the claims have not been interpreted to be limited to 90% over the full length of SEQ ID NO: 10). The sequence of Von Wintzingerode is a 16S rDNA probe which is used in the identification of environmental strains of Bacillus mycoides and is a species specific probe. Von Wintzingerode does not teach a PNA with a nucleobase containing portion identical to the sequence of Von Wintzingerode, however Hyldig Nielsen teaches species specific rRNA PNA probes for the detection of Neisseria Gonorrhoeae and Chlamydia Trachomatis. Hyldig Neilsen teaches generally that PNA probes can make good species specific probes and, due to the high affinity of PNA for nucleic acid, makes even performing a solid phase hybridization assay rapid and flexible than traditional nucleic acid probes in solid phase hybridization (see page 3, lines 27-30). Hyldig Neilsen teaches also teaches that PNA probes allow for sensitive assays to be made with shorter probes than typical nucleic acid probes today and that since PNA probes have a higher thermal instability for mismatching bases and therefor exhibit higher specificity for their complementary nucleic acids than traditionally used nucleic acid probes (see page 4, 1st para). Hyldig Neilsen generally teaches that: a) PNA probes can have general formulas (pages 9-12); b) that species specific PNA probes can be labeled (8, para 2) on one or both ends (instant claims 5, 7, and 8) with water soluble dextrans (page 13, para 1; instant claims 6, 41, 42) or fluorophores (para 2-3); c) PNA probes which are labeled on both ends can have labels that are different (page 14, para 2; instant claims 7 and 8); d) PNA probes can be unlabeled (page 14, last para; instant claims 4,

37); e) PNA probes can have preferably 8 to 20, 12-20 and most preferably 12-17 nucleobases (page 21, last para; instant claim 3); f) PNA probes can be bound to a support (page 25, lines 25-27); g) PNA probes can be contained in a kit (page 26, line 27; instant claims 36-43); h) PNA probes can be labeled with an antibody (page 26, line 26; instant claim 38) which also has a detectable moiety such as fluorescein isothiocyanate (page 31; line 11; instant claims 39 and 40); and i) PNA probes can be used in slide based analysis for in situ hybridization (example 5, pages 35-36). Therefore, it would have been prima facie obvious to the ordinary artisan at the time the invention was made to improve the nucleic acid probe of Von Wintzingerode by using the nucleobase sequence of the nucleic acid probe and constructing a PNA probe as taught by Hyldig Neilsen for the benefit of constructing an even more sensitive species specific probe. The ordinary artisan would have been motivated to improve the probe of Von Wintzingerode because Hyldig Neilsen teaches that PNA probes are superior to nucleic acid probes for specific hybridization and also when shorter probes are used. It would have been further obvious to provide the PNA probe of Von Wintzingerode in view of Hyldig Neilsen in kit format as Hyldig Neilsen teaches that kits are useful for diagnostic assays.

Conclusion

13. No claims are allowable.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0572. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

Note: The examiner's name has changed from Jehanne Souaya to Jehanne Sitton. All future correspondence to the examiner should reflect the change in name.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (571) 272-0507.

Jehanne Sitton

Jehanne (Souaya) Sitton
Primary Examiner
Art Unit 1634

1/24/04